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| EXAMINER |
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OSINSKI, BRADLEY JAMES

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/616,784
Filing Date: July 10, 2003
Appellant(s): VAN ANTWERP, WILLIAM P.

William J. Wood
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/17/2010 appealing from the Office action mailed 9/17/2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

1, 3-9 and 36-41 are rejected and pending.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

| | | |
|--------------|---------------|--------|
| 6,197,598 | Schrier et al | 3-2001 |
| 2002/0082556 | Cionata et al | 6-2002 |

Gu et al "Protection of catheter surfaces from adhesion of *Pseudomonas aeruginosa* by a combination of silver ions and lectins" World Journal of Microbiology & Biotechnology, 17: pgs. 173-179, 2001

Steinberg et al "Chemical defenses of seaweeds against microbial colonization" Biodegradation, 8: pgs 211-220, 1997

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:
Claims 1, 3-6, 8, 9 and 37-41 rejected under 35 U.S.C. 103(a) as being unpatentable over Gu et al (World Journal of Microbiology and Biotechnology) in view of Steinberg et al (Biodegradation).

- a. Regarding claim 1, Gu discloses a catheter coated with a heavy metal (page 177) that is coated with lectins capable of binding microorganisms that form a biofilm on the surface of a medical device. The lectins are disposed in a

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biodegradable polymer of cellulose acetate in acetone (see Andradý and Applicant's specification) that is capable of sloughing away from the medical device when the lectin is bound to a compound produced by a microorganism. Gu also discloses lectins may be used to enhance adhesion of bacteria that from biofilms (Page 177). While Gu substantially discloses the apparatus as claimed, it does not disclose an expectation of success if the lectins had enhanced absorption of microorganisms. However, a scientific paper by Steinberg et al discloses a brief overview of biofilm inhibition methods. One is the continuous shedding of outer layers, removing any attached epibiota (Page 213). Thus Steinberg presents evidence that increasing the absorption of bacteria on a surface that is degradable/sloughing away (as Gu gives examples of) is a way of inhibiting biofilm growth on the surface of a device/organism. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Gu to give the lectins improved adhesive properties as taught in Gu itself so as to improve biofilm inhibition of the device as known in the art via Steinberg.

b. Regarding claim 3, Cellulose acetate in acetone is a biocompatible polymer that has a controllable rate of degradation based upon the various controllable factors of the polymer (degree of substitution, amount of solvent, etc...).

c. Regarding claims 4 and 5, Gu also discloses silver ions as an as an antibiotic agent.

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- d. Regarding claim 6, Gu discloses the microorganism *Pseudomonas aeruginosa*.
- e. Regarding claim 8, The device of Gu is capable of being implanted.
- f. Regarding claim 9, Gu discloses a catheter.
- g. Regarding claim 37, Gu discloses the catheter being made of various substances, including the biostable polymeric material polytetrafluoroethylene (page 174)
- h. Regarding claim 38, see claims 1 and 37 above.
- i. Regarding claim 39, see claim 27 above.
- j. Regarding claim 40, see claim 1 above.
- k. Regarding claim 41, as the composition of Gu inhibits the attachment of *P. aeruginosa* to the mechanical structure relative to the mechanical structure not coated with the composition, it is apparent that the lectin is disposed on a region of the device having a mechanical structure that is compatible with the adherence of microorganisms.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gu et al (World Journal of Microbiology and Biotechnology) and Steinberg et al (Biodegradation) as applied to claim 1 above, and further in view of Schrier et al (6,197,598).

- l. Regarding claim 7, While Gu substantially discloses the apparatus as claimed, it does not disclose the specific lectins concanavalin A or wheat germ agglutinin. However, Schrier et al discloses concanavalin A as being a binder lectin for *Pseudomonas aeruginosa* (Col. 10 line 67 and Col.11 line 13).

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use concanavalin A as the lectin of Gu as taught by Schrier et al as concanavalin A is a known lectin that binds *Pseudomonas aeruginosa*.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gu et al (World Journal of Microbiology and Biotechnology) and Steinberg et al (Biodegradation) as applied to claim 1 above, and further in view of Cioanta et al (2002/0082556).

m. Regarding claim 36, While Gu substantially discloses the apparatus as claimed such as inhibition of bacterial attachment to steel (page 174), it does not disclose the catheter being composed partially of titanium or stainless steel. However, Cioanta discloses stainless steel as a catheter material that can utilize a material to inhibit formation of biofilms (paragraphs 102 and 121). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the biofilm of Gu with a stainless steel catheter such as that of Cionata as there is only the expectation of reducing biofilm formation upon the stainless steel catheter.

(10) Response to Argument

Appellant argues that Gu teaches a different mechanism for inhibiting microorganism attachment to medical devices than the Appellant and that the Examiner's modification teaches away from the primary reference. The Examiner disagrees since one of ordinary skill reading the entirety of Gu would be led to the device of Appellant. While Gu discusses preventing adhesion via lectins, the discussion

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section specifically states that lectins are highly specific in blocking or enhancing adhesion. This suggests to one of ordinary skill in the art that lectins may also be used to enhance adhesion of bacteria. By itself, Gu does not support the rejection, but when viewed with Steinberg (within the art of protecting surfaces against microbial growth), Applicant's device is suggested. Steinberg shows that shedding of layers with attached epibiota (Entire first paragraph of Column 1 on page 213) is a known method for preventing microbial colonization on a surface. Thus the growth of microbes on the surface of a device can be prevented either by preventing their attachment in the first place or allowing their attachment and then removing the layer they are attached to. Applicant's argument that it would render the device unsatisfactory for its intended purpose is not held to have merit since the combination achieves the same objective of preventing microbial growth on the device. Even if the board does not uphold the rejection of claims 1 and 38, the rejection of claim 7 (which depends on claim 1) should still be analyzed since it also rejects claim 1 by extension and holds its own merits.

Claim 7 is rejected under the additional reference of Schrier. Schrier is used as it cites the same lectin used by Applicant. Thus a device incorporating a specific lectin will act the same as another device with the same lectin.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

/Bradley J Osinski/

Examiner, Art Unit 3767

Conferees:

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767

/Michael Phillips/

RQAS